

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
<hr/> THIS DOCUMENT RELATES TO: <i>Wave 11 case Welch, et al. v. Ethicon, Inc., et al., 2:12-cv-08677, and all future Wave cases</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS’ REPLY BRIEF IN SUPPORT OF PLAINTIFFS’ *DAUBERT* MOTION TO
EXCLUDE THE TVT GENERAL CAUSATION OPINIONS AND
TESTIMONY OF BRUCE S. KAHN, M.D.**

COMES NOW Ethicon Wave 11 Plaintiff Tammy Welch, and all future Wave cases, by and through the undersigned attorneys, and file this Reply Brief in Support of Plaintiffs’ *Daubert* Motion to Exclude the TVT General Causation Opinions of Bruce S. Kahn, M.D., and would respectfully show the Court that certain of Dr. Kahn’s opinions should be excluded for the following reasons:

- Dr. Kahn’s “clinical experience” with the TVT ended in 2005;
- Dr. Kahn’s opinions on degradation and fraying are not based on education, experience, or reliable methodology; and
- Dr. Kahn’s opinions on pain, erosion, and exposure are not grounded in facts.

ARGUMENT

I. Dr. Kahn’s “Clinical Experience” with the Defendants’ TVT Ended in 2005.

Defendants intend to offer “expert” opinions from a doctor regarding a product that he has not used in almost fifteen years. In their Response, Defendants stress Dr. Kahn’s qualifications to opine on stress urinary incontinence and the available treatment options for stress urinary

incontinence. However, Defendants' intentions are not to limit Dr. Kahn's testimony to stress urinary incontinence and the options available for its treatment. Instead, Defendants wish to have Dr. Kahn offer general causation opinions about the TVT device and its safety and efficacy. The jury will be left wondering, as are the Plaintiffs, why this doctor has been hired to discuss the intricacies of a product he hasn't used since 2005. Dr. Kahn's role is confusing, and his testimony will not be helpful to the jury; he is an unqualified distraction.

Defendants hang on Dr. Kahn's testimony that he has implanted 2,000 polypropylene mesh retropubic slings, 200 of which were TVTs; but they refuse to acknowledge the obvious hole in his qualifications considering those 200 slings were the first 200 of 2,000. As Plaintiffs articulate in their Motion, and Defendants echo in their Response, many of Dr. Kahn's opinions—whether regarding safety and efficacy of the TVT, the TVT's IFU, or characteristics/biocompatibility of the TVT—are based upon his "clinical experience;" Dr. Kahn used that as a fallback position throughout the entirety of his deposition. The undisputed truth, though, is that Dr. Kahn's "clinical experience" is fatally lacking. His clinical experience over the last fourteen years, which is devoid of the TVT, does not serve as a sufficient basis for his causation opinions on the TVT, specifically.

The *Daubert* standard is not an impossible threshold, but it is one based in science, logic, and common sense. Here, Defendants have attempted to create an expert where one does not exist. Dr. Kahn's credentials do not meet the necessary threshold for the opinions Defendants truly intend for him to give. Plaintiffs respectfully request the Court exclude Dr. Kahn's TVT general causation opinions, because he lacks the requisite qualifications, namely his "clinical experience," to offer such opinions.

II. Dr. Kahn's Opinions on Degradation and Fraying Are Not Based on Education, Experience, or Reliable Methodology.

No matter what creative arguments Defendant conjure, they must live with Dr. Kahn's testimony that he had not heard of degradation and fraying until Defendants hired him. Defendants also cannot create an expert with nothing more than an internet browser. Dr. Kahn, without hesitation or equivocation, testified that he "honestly had to learn a lot about" degradation and fraying because "in reviewing some of the plaintiffs' expert reports, a lot of that information was new information." He then doubled-down: "this was all kind of things that I hadn't really heard much about in the past, [s]o I did spend a fair amount of time seeing – searching out to see what there was that I could find... So mostly internet searches... But I can't remember any specific for you, but that's the basic mechanism. It was basically using an internet search." *See* Plaintiffs' Mem. at 8-9 (*quoting Deposition of Bruce S. Kahn*).

Defendants unsuccessfully attempt to spin this in their favor. They cite to Dr. Kahn's statement that "[he] hadn't had any clinical problems" with degradation or fraying, and they claim this supports his opinions. However, there is a critical distinction between not seeing something for which you are actively looking and not seeing something for which you are *not* looking. Dr. Kahn was never looking for these issues because he did not know to look for them; moreover, since learning about these issues, he has not had the opportunity to look for them. He attempted to dodge further questions about these subjects, which only further shows his lack of qualification:

Q: Were you looking for fraying of the TVT product when you began implanting it in 2000?

A: Again, my answer would be that I was looking for any complications that my patients may have. Fraying was not something that – unless I was looking for it, but if fraying were causing problems for my patients, I certainly would be interested in looking at that, and I was looking carefully to see if my patients were having any problems with their surgery.

...

Q: Okay. Were you looking specifically for fraying of the mesh when you began implanting it in 2000?

A: I was looking for problems – any problems my patient might be having with the surgery?

Q: Did you know to look for fraying of the TVT product?

A: I was looking for their clinical outcomes...

See Defendants' Mem. at 9-10 (*quoting Deposition of Dr. Bruce S. Kahn*). Dr. Kahn was even given the opportunity to clarify his testimony:

Q: Doctor, do you want to change your testimony earlier about fraying being a new concept to you when you began your work in this case?

...

A: No, I don't think I need to.

See Ex. B to Defendants' Mem.: Kahn Dep., at 102:18-23. If Dr. Kahn were asked at trial by Defendants whether he had ever seen degradation or fraying of a TVT in his practice; presumably, his answer would be no. If he were then asked whether he was looking for fraying or degradation; any answer other than 'no' would be an outright lie. Thus, his opinions on degradation and fraying are not useful or helpful to the jury.

Dr. Kahn clearly testified that these were new concepts to him when Defendants hired him. To allow an individual to opine as an expert on subjects with which he was not familiar until being hired as an "expert" would insult the foundation of *Daubert*. Defendants were charged with finding a qualified expert to give the opinions they wanted; they failed to meet their burden. Therefore, the Court should exclude all of Dr. Kahn's opinions and testimony concerning fraying and degradation of the mesh.

III. Dr. Kahn's Opinions on Pain, Erosion, and Exposure Are Not Grounded in Facts.

Defendants confuse Plaintiffs' argument in their Response. In his report, Dr. Kahn opined that pelvic pain, vaginal pain, and dyspareunia—as well as erosions and exposures—are not caused by *either* a defect in the TVT device *or* an inherent characteristic of the TVT device. *See* Ex. A to Plaintiffs' Mem: Kahn TVT General Report at 18. In their Response, Defendants focus on the 'defect in the TVT' portion of this Dr. Kahn's opinion. First, this is an improper legal conclusion that Dr. Kahn is not allowed to make. Second, Plaintiffs' argument focuses on the 'inherent characteristic' portion of the opinion; and this opinion is not grounded in facts, evidence, or common sense:

Q: The next sentence: "The risk of mesh exposure or erosion is arguably unique to mesh-based surgeries, but suture exposures or graft exposures can occur with non-mesh based procedures too."

Did I read that right?

A: Yes.

Q: Why are – why is mesh exposure or mesh erosion arguably unique to mesh-based surgeries?

A: It – because it's mesh. You know, mesh – when we talk about a mesh exposure, it's mesh...

So mesh – you know, synthetic mesh erosion is unique. That's all I was – there's nothing – there's nothing deep there. Simply that it's mesh that's unique to it...

See Ex. C, attached hereto, at 177:178:3. Dr. Kahn contradicts his own opinion and clarifies why his opinions regarding "inherent characteristics of mesh" are nonsensical. Of course, mesh erosions and exposures are caused by an inherent characteristic of mesh—Why? As Dr. Kahn so eloquently put it: "because it's mesh." The same goes for pain and dyspareunia.

Therefore, the Court should exclude Dr. Kahn's opinions that pelvic pain, vaginal pain, dyspareunia, erosion, and exposure are not caused by any inherent characteristic of the mesh.

CONCLUSION

WHEREFORE, PREMISES CONSIDERED, Plaintiffs respectfully request that the Court grant their Motion to Exclude the TVT General Causation Opinions of Bruce S. Kahn, M.D. Additionally, Plaintiffs request all other and further relief to which they may be justly entitled.

Dated: September 5, 2019

Respectfully submitted,

/s/ Jim M. Perdue, Jr.

Jim M. Perdue, Jr., Esq.

PERDUE & KIDD

777 Post Oak Blvd, Suite 450

Houston, Texas 77056

Tel: (713) 520-2500

Fax: (713) 520-2525

jperduejr@perdueandkidd.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on September 5, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Jim M. Perdue, Jr.
Jim M. Perdue, Jr., Esq.
PERDUE & KIDD
777 Post Oak Blvd, Suite 450
Houston, Texas 77056
Tel: (713) 520-2500
Fax: (713) 520-2525
jperduejr@perdueandkidd.com